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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,771	12/05/2005	Mohammad Reza Mehrabi	TOMK0004	9945
25235 7590 11/30/2007 HOGAN & HARTSON LLP ONE TABOR CENTER, SUITE 1500 1200 SEVENTEENTH ST DENVER, CO 80202			EXAMINER THOMAS, TIMOTHY P	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 11/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,771	Applicant(s) MEHRABI, MOHAMMAD REZA	
	Examiner Timothy P. Thomas	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. The previous restriction requirement of 9/26/2007 is withdrawn. A new restriction requirement follows.
2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to a medicament.

Group II, claim(s) 1-12, drawn to a method of stimulating angiogenesis.

Group III, claim(s) 1-2, and 7-12, drawn to a method of treating a disease or condition.

Use claims, such as claims 1-12, can be interpreted as either product or method claims. Additionally, the method claims can be interpreted in various ways, reflected by the above groups.

3. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature common to the claims is alprostadil or alprostadil associated with angiogenesis. Diaz-Flores, et al. (The Anatomical Record; 1994; 238:68-76; IDS reference) teaches PGE1 induces capillary sprouting from veins in soft

connective tissue from the rat femoral vein and neovascularization (abstract). Since the technical feature has been disclosed in the prior art, the technical feature does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If applicant elects Group I, an election of a treatment specie is required from the species recited in (a)-(l) of Claim 13; or

If applicant elects Group II, an election of a specific condition or disease that the angioneogenesis is used for is required from the following:

- (i) treatment of cardiomyopathy (claim 2);
- (ii) treatment of chronic heart failure (claim 2);
- (iii) treatment of (i) and (ii) (claim 2);
- (iv) neovascularization (claim 3);
- (v) reduction of the degree of fibrosis (claim 4);
- (vi) regression of hypertrophy (claim 5);
- (vii) revitalization of dead areas of the heart (claim 6);
- (viii) treatment of advanced peripheral arterial occlusive diseases (claim 7) (if elected, specify a single disclosed disease);

- (ix) treatment of diabetic angiopathy (claim 8);
- (x) treatment of pulmonary fibrosis (claim 9);
- (xi) treatment of systemic lung disorders, not included in (x) (claim 9) (if elected, specify a single disclosed systemic lung disorder);
- (xii) treatment of renal failure and glomerulonephritis (claim 10);
- (xiii) treatment of hepatic failure (claim 11);
- (xiv) treatment of cerebral infarction (claim 12); or
- (xv) any other singly disclosed condition or disease not in (i)-(xv) (specify the specific condition or disease) (claim 1); or

If applicant elects Group III, an election of a specific condition or disease to be treated is required from the following:

- (i) cardiomyopathy (claim 2);
- (ii) chronic heart failure (claim 2);
- (iii) (i) and (ii) (claim 2);
- (iv) advanced peripheral arterial occlusive diseases (claim 7) (if elected, specify a single disclosed disease);
- (v) diabetic angiopathy (claim 8);
- (vi) pulmonary fibrosis (claim 9);
- (vii) systemic lung disorders, not included in (x) (claim 9) (if elected, specify a single disclosed systemic lung disorder);
- (viii) renal failure and glomerulonephritis (claim 10);
- (ix) hepatic failure (claim 11);

- (x) cerebral infarction (claim 12); or
- (xi) any other singly disclosed condition or disease not in (i)-(xi) (specify the specific condition or disease) (claim 1).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

The specific conditions correspond to the claims designated above

The following claim(s) are generic: claims 1, 2 and 13.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As pointed out above the prior art has disclosed neovascularization associated with the administration of

PGE1 to tissues surrounding rat femoral vein. Therefore the technical feature common to the species does not constitute as special technical feature and as it does not define a contribution over the prior art; the species are not linked by the same or a corresponding special technical feature as to form a single inventive concept.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention..

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

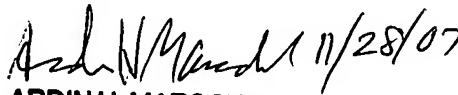
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TPT/
Timothy P. Thomas
Patent Examiner


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER